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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/809,236	03/25/2004	Mehran Bashiri	S63.2P-11058-US02	9063

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EXAMINER	
SONNETT, KATHLEEN C	

ART UNIT	PAPER NUMBER
3731	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/809,236	BASHIRI ET AL.	
	Examiner	Art Unit	
	KATHLEEN SONNETT	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 July 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3,8-24,26-30,33-37 and 40-45* is/are pending in the application.

4a) Of the above claim(s) *41-43* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3,8-24,26-30,33-37,40,44 and 45* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 6/19/2008 has been entered.

2. Claims 1, 3, 8-24, 26-30, 33-37, and 40-45 are pending. Claims 41-43 are withdrawn.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claim 23 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 23 includes that the backbone is at least one wire. However, clam 1 includes that the single backbone is a single strut. Therefore, it appears that claim 23 should read that the backbone is a wire, not "at least one wire" since the backbone cannot be made from more than strut.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. **Claims 1, 20-24, 26-30, and 33** are rejected under 35 U.S.C. 103(a) as being unpatentable over Callol (US 6,585,757) in view of Globerman (US 6,428,570). Callol discloses a stent assembly comprising a stent, the stent having proximal and distal ends and being configurable between an unexpanded and expanded state, the stent comprising a single stent backbone (18) which extends from the proximal to the distal end of the stent, the stent backbone being oriented in a direction which is substantially parallel to a longitudinal axis of the stent, the stent backbone being a single strut and a plurality of interconnected first stent members and second stent members, the first stent members (16) being oriented in a substantially longitudinal direction in the unexpanded and expanded state, each of the second stent members (straight portion of 14) being oriented in a substantially longitudinal direction in the unexpanded state. The stent backbone has greater column strength than the plurality of interconnected stent members because the backbone stretches the entire length of the stent. Although Callol discloses the second stent members (14) stretch open in the expanded configuration, it is not clear how circumferential the formerly longitudinally directed portions of (14) become in the expanded configuration.

7. Globerman discloses that it is well known in the art to fully expand a similarly wavy strut so that portions of the strut that are longitudinally directed when a stent is in its unexpanded state become circumferentially directed in the stent's expanded configuration (figs. 14, 15). This allows the stent to have a greater radial expansion ratio and therefore the stent can treat a larger vessel while having a very small unexpanded profile. It would have been well within the purview of one skilled in the art to use second stent members (14) that expand in the manner taught by Globerman on the device of Callol so that it too would have this advantage.

8. Regarding claim 20, although not expressly disclosed by Callol, therapeutic coatings on stents are well known in the art for increasing their biocompatibility and for treating surrounding tissue and such a coating would have been an obvious modification to one skilled in the art.

9. Regarding claims 21 and 22, nitinol is a shape memory material (col. 3, ll. 47 of Callol).

10. Regarding claims 23 and 24, the backbone and first and second stent members are wires.

11. Regarding claim 26, adjacent first and second stent members form closed loops.

12. Regarding claims 27 and 28, the second stent members (14) include a curved region and a straight region in the unexpanded configuration (fig. 1 of Callol).

13. Regarding claim 30, the backbone is substantially straight.

14. Regarding claim 29, Callol does not disclose that the backbone comprises at least one substantially curved portion. However, Globerman discloses including a curved portion in a longitudinally directed stent segment (see fig. 16). As is well known in the art, inclusion of a curved portion in an otherwise straight stent segment increases the flexibility of the stent. It would have been obvious to modify the device of Callol to include a curved portion in any of the straight, longitudinally directed stent members including the backbone in order to achieve greater flexibility.

15. Regarding claim 33, the backbone is radiopaque (col. 3 ll. 47-49).

16. **Claims 1, 3, 20, 23, 24, 26-28, 30, 33, and 40** are rejected under 35 U.S.C. 103(a) as being unpatentable over McGuinness (US 6,102,943) in view of Globerman. McGuiness discloses a stent assembly comprising a stent, the stent having proximal and distal ends and being configurable between an unexpanded and expanded state, the stent comprising a single stent backbone (24 and 26 welded or adhered together; figs. 1, 2a) which extends from the proximal to the distal end of the stent, the stent backbone being oriented in a direction which is

substantially parallel to a longitudinal axis of the stent, the stent backbone being a single strut and a plurality of interconnected second stent members, each of the second stent members (straight portion of 28) being oriented in a substantially longitudinal direction in the unexpanded state. The stent backbone has greater column strength than the plurality of interconnected stent members because it is thicker than any of the other stent members. Although McGuiness discloses the second stent members (28) stretch open in the expanded configuration, it is not clear how circumferential the formerly longitudinally directed portions of (28) become in the expanded configuration. McGuiness also fails to disclose first stent members that are longitudinally directed in the unexpanded and expanded state.

17. Globerman discloses that it is well known in the art to fully expand a similarly wavy strut so that portions of the strut that are longitudinally directed when a stent is in its unexpanded state become circumferentially directed in the stent's expanded configuration (figs. 14, 15). This allows the stent to have a greater radial expansion ratio and therefore the stent can treat a larger vessel while having a very small unexpanded profile. It would have been well within the purview of one skilled in the art to use second stent members (14) that expand in the manner taught by Globerman on the device of McGuiness so that it too would have this advantage. Globerman also teaches including first stent members (35; fig. 15) that are longitudinally directed in both the expanded and unexpanded stent and connect adjacent rings of the stent. These first stent members increase the structural integrity of the stent. It would have been obvious to add first stent members connecting the second stent members as taught by Globerman in order to increase the strength and structural integrity of the stent of McGuiness.

18. Regarding claim 3, the stent backbone is thicker than the first and second stent members.

19. Regarding claim 20, although not expressly disclosed by McGuiness, therapeutic coatings on stents are well known in the art for increasing their biocompatibility and for treating surrounding tissue and such a coating would have been an obvious modification to one skilled in the art.

20. Regarding claims 23 and 24, the backbone and first and second stent members are wires since they may be made from metal sheet and are therefore thin pieces of metal.

21. Regarding claim 26, adjacent first and second stent members form closed loops.

22. Regarding claims 27 and 28, the second stent members (14) include a curved region and a straight region in the unexpanded configuration (fig. 1 of McGuiness).

23. Regarding claim 30, the backbone is substantially straight.

24. Regarding claim 33, the backbone is radiopaque when radiopaque adhesive is used to join 24 and 26 to form the backbone (col. 6 ll. 19-22 of McGuiness).

25. Regarding claim 40, the stent is constructed from a tube of stent material.

26. **Claims 8-11,13-15, and 34-37** are rejected under 35 U.S.C. 103(a) as being unpatentable over Callol in view of Globerman as applied to claim 1, above, and further in view of Bashiri et al. (US 6,165,178). Callol in view of Globerman discloses the invention substantially as stated above but fails to disclose a push wire with its distal end being removably engaged to a proximal end of the stent, the first backbone extending from the distal end of the push wire.

27. Callol discloses that the stent is balloon expandable and may be made of Nitinol. It would have been obvious to program the Nitinol stent for self-expansion since such stents are very well known in the art and self-expansion reduces the number of mechanical actions that are needed to deploy the stent. When the stent is self-expandable, it can be used with the wire taught by Bashiri et al. (see fig. 15; col. 9 ll. 25-40). The push wire (194) is used to position the stent within the desired surgical site. After proper positioning, the stent is released from the

push wire when the severable junction (196) is electrolytically detached. It would have been obvious to one skilled in the art to modify Callol to make the stent self-expandable so that it can be connected to a single push wire from which it is easily released as taught by Bashiri et al. in order to minimize mechanical actions needed to deploy the stent as well as being able to temporarily implant the stent for an extended period of time. The wire is thermally and electrically conductive.

28. Regarding claims 14 and 15, it would have been obvious to one skilled in the art to construct the electrolytic detachment site to remain attached until the stent is fully deployed. Since the push wire is used to properly position the stent, it would have been obvious to keep this connection present until the stent has reached its fully deployed position. An earlier detachment might result in displacement of the stent since its configuration continues to change slightly until it is fully deployed.

29. Regarding claims 34-36, Bashiri et al. teaches forming part of the severable junctions out of radiopaque material since it is desirable to be able to visualize where the end of the implantable device is located (col. 6, ll. 44-50). Regarding claim 37, Bashiri et al. does not expressly teach a plurality of radiopaque markers but it has been held that mere duplication of the essential working parts of a device involves only routine skill in the art (*St. Regis Paper Co. v. Bemis Co.,* 193 USPQ 8).

30. **Claim 12** is rejected under 35 U.S.C. 103(a) as being unpatentable over Callol in view of Globerman and Bashiri et al. as applied to claims 8 and 11 above, and further in view of Camrud et al. (US 6,699,280). Callol as modified above discloses the invention substantially including a severable junction between the push wire and the stent but fails to disclose that the severable joint is bioabsorbable.

31. However, Camrud et al. teaches that a severable junction between two portions of an implantable medical device can be formed by a bioabsorbable connection. The bioabsorbable connection degrades upon interaction with fluids within the body lumen to a point at which the two portions break apart (col. 10, ll. 13-20). It would have been obvious to one skilled in the art to further modify Callol to substitute a bioabsorbable connection as taught by Camrud et al. with the electrolytic detachment site taught by Bashiri et al. since such a modification would have been a simple substitution of known methods of forming a severable junction between two portions of a medical device.

32. **Claims 16-19, 44, and 45** are rejected under 35 U.S.C. 103(a) as being unpatentable over Callol in view of McGuiness and Bashiri et al. as applied to claim 15 above, and further in view of Ravenscroft (US 5,702,418). Callol in view of McGuiness and Bashiri et al. discloses the invention substantially but fails to disclose that the device is configurable from the initially deployed configuration to the predeployed configuration.

33. However, Ravencroft teaches using a catheter to keep a self-expanding stent in a collapsed configuration until deployment. Ravencroft further teaches that it is advantageous to have a delivery device that allows partial deployment and retraction of the stent through an attachment at the proximal end of the stent so that the surgeon can recover a stent that is not properly positioned during deployment. It would have been obvious to one skilled in the art to house the stent with a pull wire connected to its proximal end as taught by Bashiri et al. in a catheter as taught by Ravencroft so that the stent may be partially deployed and then returned back to the predeployed position in order to gain the advantage of being able to recover an incorrectly positioned stent.

34. Regarding claims 18 and 19, the stent cannot be fully deployed at least until the entire stent is free from the catheter. As seen in fig. 15 of Bashiri et al., the very distal end of the push

wire is distal of the proximal-most portion of the stent and therefore a portion of the push wire and the stent are free of the lumen before the stent reaches its fully deployed position.

35. Regarding claims 44 and 45, it is old and well known to include radiopaque markers on catheters particularly at their distal ends and is further taught by Bashiri et al. (catheter 102; markers 106). Such a modification would have been obvious to one skilled in the art in order to monitor the position of the catheter within a patient's vasculature.

Response to Arguments

36. Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KATHLEEN SONNETT whose telephone number is (571)272-5576. The examiner can normally be reached on 7:30-5:00, M-F, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on 571-272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

KCS 10/1/2008

/Todd E Manahan/
Supervisory Patent Examiner, Art Unit 3731